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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,566	01/23/2004	Richard Franklin	20342/1202529-US1	3220

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DARBY & DARBY P.C.
P.O. BOX 770
Church Street Station
New York, NY 10008-0770

EXAMINER	
HUGHES, ALICIA R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
04/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,566	FRANKLIN, RICHARD	
	Examiner	Art Unit	
	ALICIA R. HUGHES	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,6-9,12-15,17-34,36 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,6-9,12-15,17-34,36 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 2, 3, 6-9, 12-15, 17-34, 36 and 50 are pending.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 10 February 2009 has been entered.

Applicants' argument, filed on 10 February 2009, has been fully considered and it is deemed to be persuasive regarding the previous rejection. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn.

Upon reconsideration of the pending claims, as presented, the following new rejections are applied. They constitute the complete set of rejections being applied to the instant application presently.

Claims 2, 3, 6-9, 12-15, 17-34, 36 and 50 are herein acted upon on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections – 35 U.S.C. §103

I. First 103 Rejection

Claims 2, 3, 6-9, 12, 17-20, 26-27, 32, 36 and 50 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,194,420 [hereinafter referred to as "Lang"], in view of U.S.

Patent No. 6,221,383 [hereinafter referred to as "Miranda et al"], and in further view of U.S. Patent No. 6,024,975 [hereinafter referred to as "D'Angelo et al"], for reasons set forth in this Office's Action dated 19 April 2007, 16 April 2008, and 17 November 2008 as applied to the same claims, which reasons are herein incorporated by reference, in total.

The Applicant now cites the declaration of one Dr. Gunnar Biregard to support the premise that Applicant has unexpectedly discovered that transdermally administering anagrelide to treat thrombocytopenia minimizes the adverse cardiovascular side effects observed when anagrelide is administered orally. While the Examiner appreciates Applicants' arguments, the same is not assigned patentable weight in the instant case, because these arguments do not go to the heart of the language that is the present contemplation in the claims.

Applicant also argues that the individual references do not teach each and every limitation of the claims presented. The applicant is correct in that each individual reference does not meet each and every limitation of the claims. However, a showing of obviousness does not require the same, but only a motivation or suggestion. In light of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to combine the teachings of Lang, Miranda et al, and D'Angelo to conclude that the combination of anagrelide or its salt form, along with a skin permeation enhancer, administered transdermally so as to avoid the first pass liver metabolism would be effective in the treatment of essential thromboycythemia.

Furthermore, it would have been *prima facie* obvious to one of ordinary skill in the art that the administration of a single or multiple layer formulation of an effective amount of anagrelide or an anagrelide salt and a menthol acting has a skin permeation enhancer with acrylic

adhesive with a surface area ranging from 1 to 200 square centimeters acting together as a transdermal delivery device would be effective for treating essential thrombocythemia.

Accordingly, for the above reasons, the claims are deemed properly rejected.

II. Second 103 Rejection

Claims 21-23, 28, and 30 are rejected under 35 U.S.C. 103(a) as being obvious over Lang in view of D'Angelo and in further view of U.S. Patent No. 5,133,972 [hereinafter referred to as "Ferrini et al"].

Applicant argues that while Ferrini describes topical administration, including transdermal administration, Ferrini does not describe or suggest anagrelide or the treatment of thrombocythemia.

The teachings of Lang and D'Angelo et al, *supra* and as stated in this Office's Action of 19 April 2007, 16 April 2008, and 22 October 2008 as well as the arguments herein, *supra*, are incorporated herein by reference, in total. The teachings of Ferrini et al, as noted in this Office's Action of 19 April 2007 and 22 October 2008 are incorporated herein by reference in total, also.

The Applicant now cites the declaration of one Dr. Gunnar Biregard to support the premise that Applicant has unexpectedly discovered that transdermally administering anagrelide to treat thrombocytopenia minimizes the adverse cardiovascular side effects observed when anagrelide is administered orally. While the Examiner appreciates Applicants' arguments, the same is not assigned patentable weight in the instant case, because these arguments do not go to the heart of the language that is the present contemplation in the claims.

Accordingly, for the above reasons, the claims are deemed properly rejected.

III. Third 103 Rejection

Claims 24-25, 29, 31, 33-34 and 36 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,194,420 [hereinafter referred to as "Lang"] in view of U.S. Patent No. 6,024,975 [hereinafter referred to as "D'Angelo et al"]. and in further view of U.S. Patent No. 4,847,276 [hereinafter referred to as "Yarrington"].

The teachings of Lang and D'Angelo et al, *supra* and as noted in this Office's Action of 16 April 2008 and 22 October 2008, are incorporated herein by reference. One of ordinary skill in the art would be motivated to combine the teachings of Lang and D'Angelo et al with the teachings of Yarrington, because each contains overlapping subject matter, most notably treatment of a myeloproliferative disease, particularly essential thrombocythemia.

The Applicant now cites the declaration of one Dr. Gunnar Biregard to support the premise that Applicant has unexpectedly discovered that transdermally administering anagrelide to treat thrombocytopenia minimizes the adverse cardiovascular side effects observed when anagrelide is administered orally. While the Examiner appreciates Applicants' arguments, the same is not assigned patentable weight in the instant case, because these arguments do not go to the heart of the language that is the present contemplation in the claims.

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art that the administration of 0.1 to 20 mg/kg/day of anagrelide and more particularly, 0.5 to 3 mg of anagrelide daily for at least 1 to 7 days via transdermal delivery would effectively treat essential thrombocythemia.

Request for Rejoinder

Applicant's Request for Rejoinder has been considered. However, since the examined claims are not allowable at this time, consideration of rejoinder is not deemed necessary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 A.M. until 5:00 P.M. on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application is proceeding is assigned 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/
Examiner, Art Unit 1614

/Raymond J Henley III/
Primary Examiner, Art Unit 1614